IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Børge KRINGELUM, et al.

Title: METHOD FOR SUPPLY OF STARTER CULTURES HAVING A CONSISTENT QUALITY

Appl. No.: 09/813,292

Filing Date: 3/21/2001

Examiner: Ruth A. Davis

Art Unit: 1651

Confirmation Number: 1783

APPEAL BRIEF TRANSMITTAL

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a single copy of an APPEAL BRIEF which follow the Notice of Appeal of November 6, 2006.

This application is on behalf of a Large Entity.

Pursuant to 37 C.F.R. 41.20(b)(2), the fee for filing the Appeal Brief is: $500

TOTAL FEE DUE:

Appeal Brief Fee	$500
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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date 6 February 2007 By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: Børge KRINGELUM, *et al.*

Title: **METHOD FOR SUPPLY OF STARTER CULTURES HAVING A CONSISTENT QUALITY**

Appl. No.: 09/813,292 Filing Date: 3/21/2001

Examiner: Ruth A. Davis Art Unit: 1651

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APPEAL BRIEF

Mail Stop Appeal Brief-Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under 35 U.S.C. § 134, Appellants appeal the Examiner's final decision in the final Office action dated July 7, 2006, rejecting claims 1-31. This Appeal Brief follows a Notice of Appeal filed November 6, 2006. Under the provisions of 37 C.F.R. § 41.37 and 37 C.F.R. § 1.136(a), this Appeal Brief is being filed together with one credit card payment form in the amount of $620, covering the 37 C.F.R. § 41.20(b)(2) appeal fee ($500), and the 37 C.F.R. § 1.17(a)(1) extension fee ($120). By virtue of the concurrently filed Petition for Extension of Time and payment of the prescribed fee, the appeal brief is timely filed. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (and credit any balance) to deposit account no. 19-0741.

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TABLE OF AUTHORITIES

FEDERAL CASES

I. REAL PARTY IN INTEREST

The real party in interest is Chr. Hansen A/S, Denmark, which is the assignee of each inventor's entire interest as recorded at reel/frame nos. 011916/0016.

II. RELATED APPEALS AND INTERFERENCES

No related appeals or interferences are pending. This application is the only application claiming the benefit of provisional application no. 60/191,307.

III. STATUS OF CLAIMS

Claims 1-31 are finally rejected and are the subject of this appeal.

No claims are allowed.

No claims are subject to objection.

The Final Office action dated July 7, 2006, indicates that claim 28 is rejected. Office action of July 7, 2006, p. 1, item 6. The body of the Final Office action does not indicate the ground(s) for rejecting claim 28. The Examiner is respectfully requested to clarify the present disposition of claim 28.

IV. STATUS OF AMENDMENTS

No post-final amendments or submissions were denied entry into the application. In the final Office action mailed July 7, 2006, at p. 2, the Examiner indicated entry of the amendment filed April 17.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There is one independent claim (claim 1) and one dependent claim that will be argued separately (claim 29). The citations to the specification will follow the procedure used in the Board's Standing Order for patent interferences, paragraph 110.

Independent claim 1 reads as follows:

-- 1. A method of supplying starter cultures of consistent quality at different propagation factories or plants **{p. 4, ll. 14-22}**, comprising the steps of (i) providing inoculum material comprising starter culture organism cells, **{p. 4, l. 24-p. 5, l. 22; p. 14, l. 7-p. 15, l. 27 (Ex. 1.2.1); p. 19, l. 28-p. 22, l. 7 (Exs. 2.1-2.1.2); p. 23, l. 1-p. 24, l. 20 (Ex. 3)}** (ii) allowing the starter culture cells to propagate for a period of time sufficient to produce a desired amount of said starter culture organism cells, **{p. 7, ll. 6-21; p. 8, ll. 6-9}** and (iii) harvesting the propagated cells to obtain a starter culture, **{p. 7, l. 33-p. 8, l. 4}**

wherein step (i) comprises:

(a) concentrating said inoculum material of step (i) to obtain a concentrated stock inoculum material **{p. 5, l. 26-p. 6, l. 8; p. 8, ll. 11-23; p. 15, ll. 29-34 (Ex. 1.2.1.2); p. 22, ll. 8-13 (Ex. 2.1.3)}**;

(b) dividing said concentrated stock inoculum material into subsets thereof and providing a subset to a different propagation factory or plant, each of said subsets having a quality sufficient to inoculate a cultivation medium at different propagation factories or plants, **{p. 6, l. 33-p. 7, l. 4; p. 16, ll. 1-5 (Ex. 1.2.1.2); p. 22, ll. 15-19 (Ex. 2.1.3)}** and

(c) inoculating said cultivation medium at the different propagation factory or plant with the subset of the stock inoculum material by direct, one step inoculation to produce said starter culture, **{p. 7, ll. 23-31; p. 8, l. 25-p. 9, l. 19; p. 16, ll. 5-8 (Ex. 1.2.1.2); p. 22, ll. 19-30 (Exs. 2.1.3-2.2)}**

wherein said stock inoculum material is subjected to a quality test before use **{p. 18, l. 17-p. 19, l. 16}** and is stored for at least 24 hours prior to said inoculating of the cultivation medium, **{p. 5, ll. 9-19}**

such that, when steps (ii) through (iii) are repeated with another subset of the stock inoculum material at a different propagation factory or plant, the supply of starter cultures has a consistent quality. **{p. 4, ll. 14-22}** --

Claim 29, which depends from claim 1, reads as follows:

-- 29. The method of claim 1, wherein the stock inoculum material or a subset thereof is subjected to a quality test selected from the group consisting of Test for contamination, Count of total viable cells, Determination of colony morphology, Determination of purity, Determination of metabolic activity, Phage test, API test, Resistance to bacteriophages, Determination of the content of *Listeria* species and salmonella species, DNA fingerprint, and Fermentation test. **{p. 18, l. 25-p. 19, l. 16}** --

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection for review are as follows:

A. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski and Christensen.

B. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Christensen, and Czulak.

C. The rejection of claims 1-11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Christensen, and Lizak.

D. The rejection of claims 1-7, 11-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Vanderbergh, and Matsummiya.

E. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Czulak, and Lizak.

F. The rejection of claims 1-7, 11, 17-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Rimler, and Lizak.

VII. ARGUMENT

A. The rejection of claims 1-7, 11, 17-22, 24-27 and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski and Christensen.

1. Argument for independent claim 1

a. Sing and the secondary references fail to suggest *supplying starter cultures of consistent quality at different propagation factories or plants* as recited in claim 1.

A determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying facts: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention at the time of invention, (3) the level of ordinary skill in the art, and (4) the objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). A further inquiry is whether or not a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention, not something approximating it. *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999) abrogated on other grounds by *In re Gartside*, 203 F.3d 1305, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000); *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q 580, 583 (CCPA 1974) (obviousness requires a suggestion of all, not some, elements in a claim). Here, the Examiner has not met her initial burden of establishing a prima facie case of obviousness, *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992), because the Examiner ignored an element of claim 1.

The appealed claims are directed to *a method of supplying starter cultures of consistent quality at different propagation factories or plants*. Appendix A, claim 1, ll. 1-2. The claimed method comprises, *inter alia*, steps of *(i) providing inoculum material comprising starter culture organism cells*, Appendix A, claim 1, ll. 2-3, a step comprising *(b) ... providing a subset to a different propagation factory or plant ... and (c) inoculating said cultivation medium at the different propagation factory or plant with the subset of the stock inoculum material by direct, one step inoculation to produce said starter culture.* Appendix A, claim 1, ll. 9-15.

The Examiner and Appellants agree on one point: the references of record, as illustrated by Sing and the other secondary references, do not teach a step comprising *(b) ... providing a subset to a different propagation factory or plant. See, e.g.,* Office action of July 7, 2006, first sentence of the paragraph bridging pp. 5-6 ("the references do not teach the method wherein the subsets are provided to different factories and/or plants.") The Examiner and Appellants, however, disagree on the significance of this agreed-upon point.

The Examiner, on one hand, contends that "the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method." Office action of July 7, 2006, p. 26, second full paragraph. The Examiner goes on to require Appellants to provide evidence that the culture resulted from the claimed method is different from those of the prior art. *Id.* By focusing on "the culture method," the Examiner has improperly focused on the biochemistry that can occur in a vat located in a particular factory or plant and has not focused on claim 1, which is directed to *a method of supplying starter cultures of consistent quality at different propagation factories or plants* as recited in claim 1. In other words, the Examiner ignored a claim element.

On the other hand, Appellants have noted that the rejection is fatally flawed, by virtue of the Examiner's error in restricting a claim for a multi-step process to fewer than all of the steps recited in the claim. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 U.S.P.Q. 303, 309 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984). The subject matter "as a whole" is not the biochemistry occurring in a single vat but is *a method of supplying starter cultures of consistent quality at different propagation factories or plants*. 35 U.S.C. § 103(a). Appellants have asked that the Examiner take a reasonable view of the claimed subject matter "as a whole," *see, e.g.,* Amendment April 17, 2006, p. 8, first full paragraph-*et seq.*, and along these lines, the references should be considered in their entirety, too. Yet an impasse between Appellants and the Examiner has been reached, and Board is asked to decide in favor of Appellants.

Based on the error just identified – the Examiner's ignoring claim elements – the Board at least may remand the application to the Examiner. But Appellants ask for a reversal in whole and provide more factual explanation of their position.

According to the technical background of the present specification, cultures constituted of many microbes can be used to make consumer products. Specification, p. 1, ll. 15-17. When a particular organism is introduced into a selected growth medium, the medium is "inoculated" with the particular organism. Growth of the "inoculum" (i.e., cell multiplication) occurs in stages, and the result is a microbial culture, which may be used as either an "inoculum" in another growth medium or a "starter culture" for a target cultivation medium.

The amount "inoculum" needed to "inoculate" a growth medium varies with the scale of the fermentation process. *See, e.g.*, present specification, example 1.2.2. Similarly, the amount of "inoculum" needed to act as a "starter culture" varies with the size of the target cultivation medium. *See, e.g.*, present specification, example 1.2.

Importantly, to make the amount of "starter culture" needed for the size of its target cultivation medium, Sing and the secondary references as a whole teach multiple propagation steps in multiple growth media. In other words, according to the background section of the specification, "[i]noculation material is produced in small ampoules and distributed to fermentation plants and each plant often makes several steps to be able to inoculate large fermenters in which the product is produced by fermentation." Present specification, p. 1, ll. 21-24. This "Sing-like" process may be represented in graphic fashion as follows:

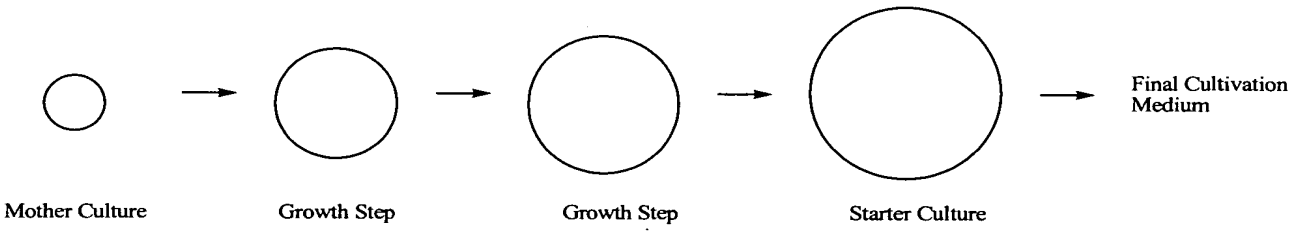

Figure 1. Conventional Direct Vat Set Starter Cultures. Spec., p. 16, ll. 10-28 (Ex. 1.2.2).

In Figure 1, the sizes of the circles represent the size (number of microbes, not drawn to scale) of a microbial culture, the "mother culture" is the microbial culture that is used in the first step to make the starter culture, the final cultivation medium is the target cultivation medium, and the arrows indicate the steps of "inoculating." Other evidence of record supports these statements. *See, e.g.*, Declaration of inventor B. Kringelum, executed February 17, 2004, entered in response to the Office action of June 28, 2004, pp. 20-21.

Before the claimed invention, therefore, an exemplary implementation of the conventional approach to making starter cultures would have entailed, first, preparing one liter of culture, by propagating bacterial cells until the growth of the cells in the medium ceased. That culture would have been transferred to another fermenter, some 100 times larger in volume (100 L), and the cells again propagated until the growth stopped. Thereafter, the resulting 100 liters of culture would have been transferred to the final fermenter, with a volume of 10,000 liters , in which the cells would have propagated until growth stopped. The cells then would have been harvested and disseminated as starter cultures for the dairy industry.

At the different plants, therefore, the conventional approach was to use 1%, measured as a volume, for inoculating the next fermenter in the sequence. Thus, the process depicted in Figure 1 occurs over and over again at each *different propagation factory or plant.* Declaration of inventor B. Kringelum at 5.

These multiple growth steps, at different factories and plants, allow multiple and unique opportunities for contamination of the growth media by other microbial organisms that can contaminate the final cultivation medium. *See* Present Specification, p. 2, ll. 1-7. Furthermore, multiple steps at different factories and plants increase the chances of a mutation of the microbial organisms in the culture at different factories and plants. Using the process of Figure 1 results in the risk of a large variation between the quality of separately produced batches within the same factory or plant (*inter-factory*) and between different factories or plants (*intra-factory*). Present Specification, p. 2, ll. 22-26.

On the other hand, claim 1 recites *supplying starter cultures of consistent quality at different propagation factories or plants*. As partially stated above, the claimed method comprises, *inter alia*, steps of *(i) providing inoculum material comprising starter culture organism cells*, a step comprising

> *(a) concentrating said inoculum material of step (i) to obtain a concentrated stock inoculum material;*
>
> *(b) dividing said concentrated stock inoculum material into subsets thereof and providing a subset to a different propagation factory or plant, each of said subsets having a quality sufficient to inoculate a cultivation medium at different propagation factories or plants,* and
>
> *(c) inoculating said cultivation medium at the different propagation factory or plant with the subset of the stock inoculum material by direct, one step inoculation to produce said starter culture.*

An embodiment of the steps *(a)-(c)* of claim 1 may be appreciated through a cartoon along the following lines:

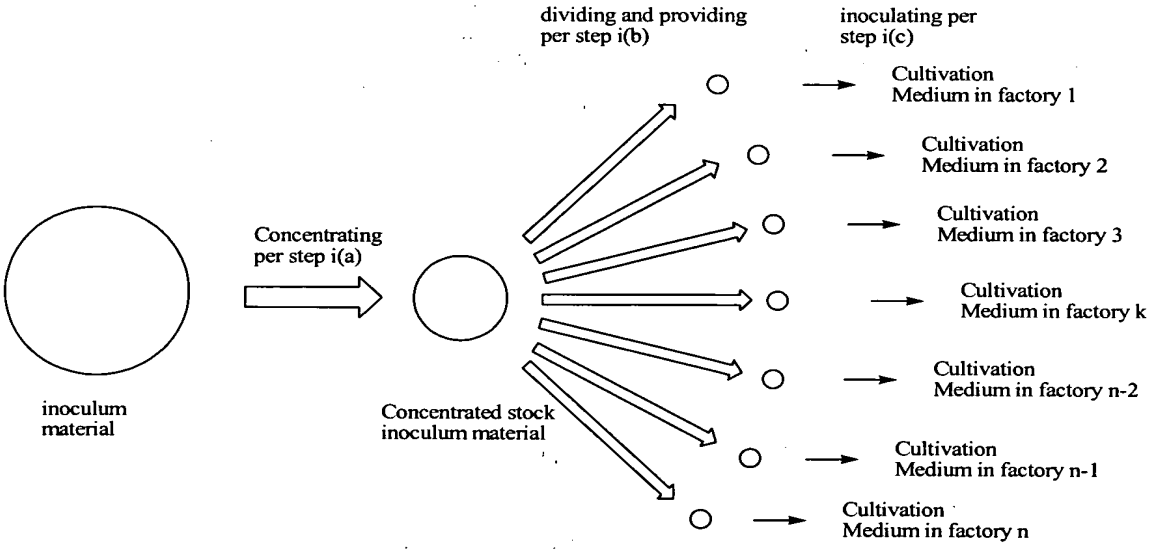

Figure 2. Representation of an Embodiment of Steps *(a)-(c)* of Claim 1.

In Figure 2, the inoculum material is concentrated and divided into n *subsets thereof* (only seven are shown). Clearly, as noted above, the Examiner and Appellants agree that references of record, as illustrated by Sing and the other secondary references, do not teach a step comprising *(b) ... providing a subset to a different propagation factory or plant. See, e.g.,* Office action of July 7, 2006, first sentence of the paragraph bridging pp. 5-6. The *subsets thereof* make it possible for *direct, one step inoculation to produce said starter culture* (right hand side of Figure 2) at various factories and/or times or at the same factory at different times, etc.[♣] The present method also makes it possible to provide *starter cultures of consistent quality at different propagation factories or plants*. Declaration of inventor B. Kringelum at 7. Finally, the different factories are rendered less vulnerable for breakdown in the process line. In the conventional approach, that is, the breakdown of a piece of equipment in the process line upstream from the final fermenter (e.g., at the 100L fermenter) meant that 10,000 liters of medium in the final fermenter would be wasted. Pursuant to the inventive process, by contrast, this situation never arises.

Although the Examiner appears to acknowledge this distinction between the cited art and claim 1, the Examiner dismissed it as immaterial. Having admitted that this distinction exists, however, the Examiner cannot simply discount, as immaterial, the fact that the claimed method yields a supply of *starter cultures of consistent quality*. To the contrary, this advantage is tied to the very distinction, admitted by the Examiner, that is without counterpart or even a hint in the prior art of record.

[♣] Claim 1 encompasses other embodiments. In conceptual terms, each presents the threshold question of whether one can proceed from concentrated stock inoculum material, as delivered to each factory, to the on-site cultivation medium. On this point, the inventors broke with conventional wisdom by virtue of their insight about the minimum cell density needed for an effective inoculum. More specifically, the inventors did calculations to illuminate the number of cells sufficient for inoculating the 10,000L fermenter, mentioned above, in a single step. Thus, they apprehended that the one-liter fermenter would contain on the order of 5×10^8 cells per gram of medium; hence, one liter would contain 5×10^{11} cells in total, constituting an inoculum for the 100L fermenter. The latter would contain 100 times more cells at the end of the propagation, i.e., 5×10^{13} cells in total, which would be transferred to the final fermenter. Accordingly, the inventors determined that 5×10^{13} cells is the target number for the one-step inoculation process, and in concentrated form these cells would have a weight of about one kilogram. With this insight, the present inventors conceived that it was feasible to replace the locally performed inoculation steps in the 1L and 100L fermenters with a 1L container of centrally produced inoculation material, pursuant to the claimed invention.

The relevant inquiry concerns the subject matter "as a whole," which is *a method of supplying starter cultures of consistent quality at different propagation factories or plants* as recited in claim 1. By not treating the subject matter as a whole, the Examiner failed to establish a prima facie case of obviousness, the evidence of record does not render claim 1 obvious, and the rejection should be reversed in whole.

b. The claimed methodology achieves a consistency of cultures, across different factories, that the cited art does not presage and that the Examiner erroneously disregarded.

As discussed in the specification, one of the issues with the conventional methodology is the high variation with regard to the quality of the fermentation end products. Present Specification, p. 2, ll. 22-26. In contrast, implementation of the claimed method allows the propagation plants located all around the world to manufacture cultures with a more consistent quality, such that all plants produce essentially the same, high quality product. *See, e.g.*, Declaration of Inventor B. Kringelum at 7; present specification at p. 16, l. 30 - p.18, l. 5.

This qualitative improvement, which the application discusses in detail under heading "1.4 Conclusion," specification, p. 17, l. 23-*et seq.*, was not realized before the present invention was implemented, possibly due to factors of cultural diversity among locally employed personnel, differences in equipment, variation as to the sorts of contamination in the different factories, *etc.* In other words, higher quality and consistency are achieved, in accordance with the claimed invention, by sending the stock inoculum material made in a single, state-of-the-art plant to the network of plants, thereby avoiding the local inoculation steps and the resulting variations in quality that were endemic to the prior art. Consequently, the claimed methodology makes it possible to control the quality at a single plant and to only release stock inoculum material that has a sufficiently high quality. Pursuant to the invention, local staff at distant plants then need only pour the stock inoculum material into a fermentor containing the cultivating medium, in a conventional manner.

Both an acknowledged difference and a resultant advantage separate the claimed invention from the prior art. Therefore, Appellants respectfully request a reversal in whole of the obviousness rejection.

2. Further Argument for claim 29

a. Claim 29 prescribes a quality test for culture viability and contamination that is readily distinguished from Christensen's test for cheese-making qualities.

Claim 29 depends from claim 1. In addition to the reasons offered above as to why claim 1 is patentable, the following reasons further support the patentability of claim 29.

The Examiner acknowledges that the primary Sing reference "does not teach the method wherein the inoculum is subjected to quality tests before use," but the Examiner relies on the secondary Christensen reference for the teaching of a quality test. Office action of July 7, 2006, p. 5, second paragraph.

Claim 29 prescribes a Markush group of the tests, including Test for contamination, Count of total viable cells, Determination of colony morphology, Determination of purity, Determination of metabolic activity, Phage test, API test, Resistance to bacteriophages, Determination of the content of *Listeria* species and salmonella species, DNA fingerprint, and Fermentation test. As disclosed in the specification, page 18, line 17-*et seq*., the purpose of the quality tests recited in the claimed method is to ensure that the starter culture is of ***high quality***, such as exhibiting high metabolic activity and high cell count, as well as ***free of contamination***. In contrast, Christensen explicitly states that the quality tests, such as acid test, activity test, test for gas, and a plate count, are to "ascertain its ***cheese-making qualities***" (column 6, lines 6-7).

As one of ordinary skill in the art would have appreciated, Christensen's quality tests are entirely different from the quality tests of the claimed method in the aspects of type, standard and purpose. Therefore, it is erroneous for the Examiner to equate the quality tests of the claimed invention with those of Christensen. It is also improper for the Examiner to combine these references, which teach quality tests in different contexts, as the required motivation to combine

is clearly lacking. Moreover, one of ordinary skill in the art would not have found it obvious to arrive at the method of claim 29, armed with the teachings of Sing and Christensen. Accordingly, Appellants ask that the rejection be reversed in whole.

B. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. §103(a) over Sing in view of Kosikowski, Christensen, and Czulak.

1. Argument for independent claim 1

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Czulak were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 9, first two full paragraphs. The Examiner even agrees that Czulak fails to teach a step comprising *(b) ... providing a subset to a different propagation factory or plant. See, e.g.,* Office action of July 7, 2006, p. 9, first full paragraph. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

2. Argument for dependent claim 29

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Czulak were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 9, first two full paragraphs. Thus, for this reason and the reasons advanced in section VI A, the present rejection should be reversed in whole.

C. The rejection of claims 1-11, 17-22, 24-27, and 29-31 under 35 U.S.C. §103(a) over Sing in view of Kosikowski, Christensen, and Lizak.

1. Argument for independent claim 1

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render the present invention obvious. Those reasons apply with equal

force here. Furthermore, the teachings of Lizak were not applied to remedy the deficiencies of the other references. Office action of July 6, 2006, p. 13, first two full paragraphs. The Examiner even agrees that Lizak fails to teach a step comprising *(b) ... providing a subset to a different propagation factory or plant. See, e.g.,* Office action of July 7, 2006, p. 13, first full paragraph. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

2. Argument for dependent claim 29

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Lizak were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 13, first two full paragraphs. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

D. The rejection of claims 1-7, 11-22, 24-27, and 29-31 under 35 U.S.C. §103(a) over Sing in view of Kosikowski, Vanderbergh, and Matsummiya.

1. Argument for independent claim 1

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Vanderbergh and Matsummiya were not applied to remedy the deficiencies of the other references. Office action, p. 17, first two full paragraphs. The Examiner even agrees that Vanderbergh and Matsummiya fail to teach a step comprising *(b) ... providing a subset to a different propagation factory or plant.* Office action of July 7, 2006, p. 17, first full paragraph. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

2. Argument for dependent claim 29

Although Christensen is not mentioned in the caption of the rejection in the Office action of July 7, 2006, p. 14, it is applied in the body of the rejection Office action of July 7, 2006, p. 16, bridging paragraph. Clarification is requested.

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Vanderbergh and Matsummiya were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 17, first two full paragraphs. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

E. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. §103(a) over Sing in view of Kosikowski, Czulak, and Lizak.

1. Argument for independent claim 1

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Czulak and Lizak were not applied to remedy the deficiencies of the other references. Office action, p. 21, first two full paragraphs. The Examiner even agrees that Czulak and Lizak fail to teach a step comprising *(b) ... providing a subset to a different propagation factory or plant.* Office action of July 7, 2006, p. 21, first full paragraph. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

2. Argument for dependent claim 29

Although Christensen is not mentioned in the caption of the rejection in the Office action of July 7, 2006, p. 18, it is applied in the body of the rejection Office action of July 7, 2006, p. 20, bridging paragraph. Clarification is requested.

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render the present invention obvious. Those reasons apply with equal force here. Furthermore, the teachings of Czulak and Lizak were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 21, first two paragraphs. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

F. The rejection of claims 1-7, 11, 17-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Rimler and Lizak.

1. Argument for independent claim 1

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render the present invention obvious. Those reasons apply with equal force here. Furthermore, the teachings of Rimler and Lizak were not applied to remedy the deficiencies of the other references. Office action, p. 24, bridging paragraph to p. 25, first full paragraph. The Examiner even agrees that Rimler and Lizak fail to teach a step comprising *(b) ... providing a subset to a different propagation factory or plant.* Office action of July 7, 2006, p. 24, last two lines. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

2. Argument for dependent claim 29

Although Christensen is not mentioned in the caption of the rejection Office action of July 7, 2006, p. 22, it is applied in the body of the rejection Office action of July 7, 2006, p. 24, bridging paragraph. Clarification is requested.

In section VI A, Appellants explained why the teachings of Sing in view of Kosikowski and Christensen fail to render obvious the present invention. Those reasons apply with equal force here. Furthermore, the teachings of Rimler and Lizak were not applied to remedy the deficiencies of the other references. Office action of July 7, 2006, p. 24 bridging paragraph to p. 26, l. 2. Thus, for this reason and the reasons advanced in section VI A, Appellants ask that the present rejection be reversed in whole.

CONCLUSION

For the reasons discussed above, Appellants respectfully submit that all pending claims are in condition for allowance, and respectfully request that the rejections be reversed in whole, and that the claims be allowed to issue.

Respectfully submitted,

Date 6 February 2007 By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicants
Registration No. 29,768

VIII. APPENDIX A: CLAIMS APPENDIX

1. A method of supplying starter cultures of consistent quality at different propagation factories or plants, comprising the steps of (i) providing inoculum material comprising starter culture organism cells, (ii) allowing the starter culture cells to propagate for a period of time sufficient to produce a desired amount of said starter culture organism cells, and (iii) harvesting the propagated cells to obtain a starter culture,

wherein step (i) comprises:

(a) concentrating said inoculum material of step (i) to obtain a concentrated stock inoculum material;

(b) dividing said concentrated stock inoculum material into subsets thereof and providing a subset to a different propagation factory or plant, each of said subsets having a quality sufficient to inoculate a cultivation medium at different propagation factories or plants, and

(c) inoculating said cultivation medium at the different propagation factory or plant with the subset of the stock inoculum material by direct, one step inoculation to produce said starter culture,

wherein said stock inoculum material is subjected to a quality test before use and is stored for at least 24 hours prior to said inoculating of the cultivation medium,

such that, when steps (ii) through (iii) are repeated with another subset of the stock inoculum material at a different propagation factory or plant, the supply of starter cultures has a consistent quality.

2. A method according to claim 1, wherein the inoculum material provided in step (i) is in quantities sufficient to inoculate at least 50,000 litres of cultivation medium.

3. A method according to claim 1, wherein the concentrated stock inoculum material provided in step (a) contains at least 10^8 CFU per g.

4. A method according to claim 1, wherein the subset of the stock inoculum material in step (c) is directly inoculated in the cultivation medium at a rate of maximum 0.1%.

5. A method according to claim 1, wherein the amount of the subset of the stock inoculum material for direct inoculation of the cultivation medium in step (c) provides a ratio of the CFU per g of cultivation medium, immediately after inoculation, relative to the CFU per g of the subset of the stock inoculum material being inoculated, said ratio being in the range from 1:100 to 1:100,000.

6. A method according to claim 1, wherein the cultivation medium immediately after the inoculation in step (c) contains a number of CFU per g of cultivation medium which is at least 10^5.

7. A method according to claim 1, wherein the cultivation medium in step (ii) comprises any conventional medium used for propagation of microbial cells.

8. A method according to claim 1, wherein the inoculum material and/or the subset of the stock inoculum material is in a state selected from the group consisting of a liquid, frozen and dried state.

9. A method according to claim 8, wherein the frozen subset of the stock inoculum material is thawed before direct inoculation of the cultivation medium in step (c).

10. A method according to claim 8, wherein the subset of the stock inoculum material is combined with an aqueous medium to obtain a suspension of the cells before direct inoculation of the cultivation medium in step (c).

11. A method according to claim 1, wherein the direct inoculation of the cultivation medium in step (c) is provided under aseptical conditions or under substantially aseptical conditions.

12. A method according to claim 1, wherein the stock inoculum material is supplied in sealed enclosures.

13. A method according to claim 12, wherein the sealed enclosures are made of a flexible material selected from the group consisting of a polyolefin, a substituted olefin, a copolymer of

ethylene, a polypropylene, a polyethylene, a polyester, a polycarbonate, a polyamide, an acrylonitrile and a cellulose derivative.

14. A method according to claim 12, wherein the sealed enclosed are made of a flexible material comprising a metal foil.

15. A method according to claim 12, wherein the sealed enclosures have a cubic content of at least 0.01 litre.

16. A method according to claim 12, wherein the sealed enclosures are supplied with outlet means for connection of the enclosure to a container comprising the cultivation medium, said outlet means permitting the concentrate of cells to be introduced substantially aseptically into the container to inoculate the cultivation medium with said concentrate of cells.

17. A method according to claim 1, wherein the starter culture organism in step (i) originates from a species selected from the group consisting of a lactic acid bacterial species, a *Bifidobacterium* species, a *Propionibacterium* species, a *Staphylococcus* species, a *Micrococcus* species, a *Bacillus*, species, an *Actinomycetes* species, a *Corynebacterium* species, a *Brevibacterium* species, a *Pediococcus* species, a *Pseudomonas* species, a *Sphingomonas* species, a *Mycobacterium* species, a *Rhodococcus* species, an *Enterobacteriaceae* species, a fungal species and a yeast species.

18. A method according to claim 17, wherein the lactic acid bacterial species is selected from the group consisting of *Lactococcus* spp., *Lactobacillus* spp., *Leuconostoc* spp., *Pediococcus* spp., *Oenococcus* spp. and *Streptococcus* spp..

19. A method according to claim 1, wherein the inoculum material in step (i) comprises at least two starter culture strains.

20. A method according to claim 1, wherein the starter culture is a starter culture used in the food industry, feed industry or pharmaceutical industry.

21. A method according to claim 1, wherein the starter culture is used for inoculation of milk which is further processed to obtain a dairy product, which is selected from the group consisting of cheese, yogurt, butter, inoculated sweet milk and a liquid fermented milk product.

22. A method according to claim 1, wherein the cells being propagated in the cultivation medium express a desired gene product or produce a desired product.

23. A method according to claim 22, wherein the desired gene product is selected from the group consisting of enzymes, pharmaceutically active substances, polysaccharides and amino acids.

24. A method according to claim 22, wherein the desired product is selected from the group consisting of pigments, flavouring compounds, emulsifiers, vitamins, growth-stimulating compounds, food additives and feed additives.

25. A method according to claim 7, wherein the medium comprises one or more single milk components.

26. The method of claim 25, wherein one or more single milk components include skimmed milk.

27. The method of claim 1, wherein steps (ii) through (iii) are repeated with another subset of the stock inoculum material and wherein the supply of starter cultures resulting from each inoculation has a consistent quality.

28. The method of claim 1, wherein step (b) comprises providing a plurality of said subsets to different propagation factories or plants.

29. The method of claim 1, wherein the stock inoculum material or a subset thereof is subjected to a quality test selected from the group consisting of Test for contamination, Count of total viable cells, Determination of colony morphology, Determination of purity, Determination of metabolic activity, Phage test, API test, Resistance to bacteriophages, Determination of the content of *Listeria* species and salmonella species, DNA fingerprint, and Fermentation test.

30. The method of claim 1, wherein the stock inoculum material is stored for at least 48 hours prior to being added to the cultivation medium.

31. The method of claim 1, wherein the stock inoculum material or a subset thereof is transported or shipped to the different propagation factory or plant in a sealed enclosure.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Chr. Hansen A/S	Examiner:	Davis, Ruth A
Serial #:	09/813,292	Group art unit:	1651
Filed:	21 March 2001	Docket:	030307-197
Title:	Method for supply of starter cultures having a consistent quality		

AD
m/04

DECLARATION BY BØRGE KRINGELUM

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Børge Kringelum having my residence at Vårbuen 48, DK-2750 Ballerup, Denmark, does state and declare as follows:

1. I am an employee at Chr. Hansen A/S, the assignee of the above patent application, and I hold a position as a dairy engineer. Furthermore, I am one of the inventors of the present invention.

2. I am a person skilled in the art to which the above application pertains.

3. I have read and understood the pending claims in that application as well as the office action related thereto dated November 5, 2003, and have the following comments:

4. I have collected data from our propagation factories in the United States to demonstrate that the claimed method according to the invention provides an unexpected advantage over the conventional method of making commercial starter cultures and thus involve a great economic benefit.

5. The conventional method of producing batches of commercial starter cultures begins for each batch at each different propagation factory with a stepwise propagation, i.e. in general two propagation steps, of cells contained in a mother culture of the cell, in order to be able to produce the necessary amount of inoculum material for the inoculation of the final inoculum medium to obtain the desired commercial starter culture.

According to the method of the present invention, batches of commercial starter cultures were produced by using subsets of a stock inoculum material for a direct one-step inoculation of the final inoculum medium to obtain the desired commercial starter cultures. All used subsets originate from the same stock inoculum material produced at our central propagation factory in Denmark.

6. A number of 457 batches of commercial starter culture produced by the conventional method were compared with 115 batches produced by the method of the invention with regard to percentage approved batches.

A batch is said to be approved if the number of cells and the metabolic activity fulfil specified requirements for approval. Furthermore, the test results for bacterial contamination must be passed, in order to get the final approval. If a batch of starter culture is not approved, the batch is to be discarded.

The following starter cultures were used in the above comparison example:

- *B. bifidum* strain

- Mixed cultures R-603 and R-604 comprising *L. lactis* subsp. *lactis* and *L. lactis* subsp. *cremoris*
- *L. acidophilus* strains LA1 and LAK
- *L. pentosus* strain LP-1
- *Pediococcus cerevisiae* strain PC3

7. The achieved results are summarised in Table 1. It appears that product approval is increased by 5.25% as a consequence of producing the batches according to the claimed invention, i.e. batches are produced from subsets from the same stock inoculum material and inoculated into the final inoculum medium by a one-step inoculation procedure.

Under the probable assumption that the increased approval rate of 5.25% resulting from a production period lasting two years is representative for our production factories world-wide, a total global cost saving of 1.5 million US$ per year is predictable.

Thus, using the new method the direct production cost is reduced substantially compared to that of the conventional method, mainly because the stepwise propagation of the cells is omitted at the individual propagation factories, which implies that we can be certified that the inoculum (i.e. subset) used for the inoculation of the final inoculum medium has is uncontaminated and has a desired consistent quality, enabling production of commercial starter culture with a higher approval rate. Thus, fewer batches have to be discarded. The implementation of the new method in our propagation factories implies also a great advantage in managing the planning of the production work as the new method generates a high degree of flexibility.

Table 1. Percentage approved batches of commercial starter culture produced by the conventional method and batches produced by the method according to the invention

Starter culture	No. of batches produced by conventional method	No. of batches produced by method of the invention	% approved batches produced by conventional method	% approved batches produced by method of the invention
B. bifidum	8	5	38	100
R-603	80	7	79	67
R-604	127	15	84	88
LA1	73	48	84	89
LAK	93	23	78	82
LP1	32	6	91	100
PC3	44	11	87	100
Total	457	115	-	-

8. I hereby declare that all statements made herein, which are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United State Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 02 - 17 - 2004 Name: Børge Kringelum
month/day/year

IX. APPENDIX B: EVIDENCE APPENDIX

Declaration of inventor B. Kringelum executed Feb. 17, 2004, entered in the Office action of June 28, 2004, pp. 20-21;

U.S. Patent No. 6,146,667 to Sing, applied in the Office action of July 7, 2006, p. 3;

U.S. Patent No. 5,098,721 to Kosikowski, applied in the Office action of July 7, 2006, p. 3;

U.S. Patent No. 3,483,087 to Christensen *et al.*, applied in the Office action of July 7, 2006, p. 3;

U.S. Patent No. 4,476,143 to Czulak, applied in the Office action of July 7, 2006, p. 6;

U.S. Patent No. 5,952,020 to Lizak, applied in the Office action of July 7, 2006, p. 10;

U.S. Patent No. 6,068,774 to Vanderbergh, applied in the Office action of July 7, 2006, p. 14;

U.S. Patent No. 5,225,346 to Matsummiya, applied in the Office action of July 7, 2006, p. 18; and

U.S. Patent No. 3,980,523 to Rimler, applied in the Office action of July 7, 2006, p. 22.

X. APPENDIX C: RELATED PROCEEDINGS APPENDIX

No related proceedings are pending.